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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,296	07/28/2003	Yasunori Kawate	11333/25	6488

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EXAMINER	
GABEL, GAILENE	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 08/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/629,296	KAWATE, YASUNORI	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *13 and 26-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 14-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-32* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/28/03; 7/12/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-12 and 14-25, with traverse, filed on July 6, 2006 is acknowledged and has been entered. Claims 13 and 26-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being claims drawn to a non-elected invention. Currently, claims 1-32 are pending. Claims 1-12 and 14-25 are under examination.

2. Applicant traverses the restriction requirement on the basis that independent claims 27 and 28 are merely narrower and broader versions of claim 1, but nevertheless recite claims that are closely related together. Applicant therefore contends that any additional search made if the two other claims are examined, is sufficiently small and presents no additional burden on the Examiner.

In response, Applicant's argument is not persuasive because each one of claims 27 and 28 recites structural and functional requirements that are not encompassed by Group I, i.e. measurement of forward angle light scatter and a physical property, and nor do they closely relate in structure and use to the currently elected claims. Accordingly, literature search for each apparatus would be distinct since the structural requirements of each invention are caused to be different. While searches would be expected to overlap by virtue of commonality of certain recited features, there is no

reason to expect the searches to be coextensive. Accordingly, the restriction requirement is being maintained.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 2-4, 7, 9, 10-12, 15-17, 20, and 22-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is vague and indefinite because it is unclear how "the reagent [which] comprises an antibody or an antigen" is part of an analyzer. Reagent compositions are generally elements used in an assay.

Claim 3 is vague and indefinite because it is unclear how "the reagent [which] comprises carrier particles sensitized with an antibody or an antigen" is part of an analyzer. Reagent compositions are generally elements used in an assay.

Claim 4 is vague and indefinite because it is unclear how "the reagent [which] comprises a fluorescent dye" is part of an analyzer. Reagent compositions are generally elements used in an assay.

Claim 7 appears incomplete in reciting, "the analyzing portion counts". What does the analyzing portion count?

Claim 9 is ambiguous in reciting, "the analyzing portion corrects an immunoassay result" because it is unclear what is encompassed by the recitation of "an immunoassay result". Does Applicant intend to encompass a concentration of the substance or a blood cell count, for example.

Claim 10 is ambiguous in reciting, "the analyzing portion ... corrects the immunoassay result" because it is unclear what is encompassed by the recitation of "the immunoassay result". Does Applicant intend to encompass a concentration of the substance or a blood cell count, for example.

Claim 11 lacks clear antecedent basis in reciting, "the particle in the assay sample". Is "the particle" the same as the "carrier particle" in claim 3.

Claim 12 lacks clear antecedent basis in reciting, "the particle in the assay sample". Is "the particle" the same as the "carrier particle" in claim 3.

Claim 15 is vague and indefinite because it is unclear how "the reagent [which] comprises an antibody or an antigen" is part of an analyzer. Reagent compositions are generally elements used in an assay.

Claim 16 is vague and indefinite because it is unclear how "the reagent [which] comprises carrier particles sensitized with an antibody or an antigen" is part of an analyzer. Reagent compositions are generally elements used in an assay.

Claim 17 is vague and indefinite because it is unclear how "the reagent ... [which] comprises a fluorescent dye" is part of an analyzer. Reagent compositions are generally elements used in an assay.

Claim 20 appears incomplete in reciting, "the analyzing portion counts". What does the analyzing portion count?

Claim 22 is ambiguous in reciting, "the analyzing portion corrects an immunoassay result" because it is unclear what is encompassed by the recitation of "an immunoassay result". Does Applicant intend to encompass a concentration of the substance or a blood cell count, for example.

Claim 23 is ambiguous in reciting, "the analyzing portion ... corrects the immunoassay result" because it is unclear what is encompassed by the recitation of "the immunoassay result". Does Applicant intend to encompass a concentration of the substance or a blood cell count, for example.

Claim 24 lacks clear antecedent basis in reciting, "the particle in the sample for immunoassay". Is "the particle" the same as the "carrier particle" in claim 16.

Claim 25 lacks clear antecedent basis in reciting, "the particle in the sample for immunoassay". Is "the particle" the same as the "carrier particle" in claim 16.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 2, 4, 7, 9-12, 14, 15, 17, 20, and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Rodriguez et al. (US Patent 6,228,652).

Rodriguez et al. disclose an analyzer which comprises a sample preparing portion (means) for subjecting samples to reagent, a light source (optical means) for irradiating the assay sample, light detectors for detecting a first optical information (radiation scattered) from irradiated blood cells and a second optical information (fluorescence) from fluorescence-labeled cell surface antigens in different subsets of cells, and analyzing portions (means) 1) for counting and differentiating between blood cell types and also 2) for determining concentration of different fluorescent-labeled cell surface antigens (assay substances) (see column 4, line 28 to column 5, line 18 and column 5, lines 34-47). The sample preparing portion is configured to subject a first and

a second aliquot of samples (or a plurality of such aliquots) to different reagents. Rodriguez et al. teach subjecting each individual aliquot to different reagents such as fluorescent dyes and fluorescent-labeled monoclonal antibodies specific for the analyte (cell surface antigens: CD4 and CD8) to be assayed or specific for blood cell surface markers in order to stain different blood cells (see column 7, line 59 to column 8, line 20 and column 11, line 46 to column 12, line 2). The light source may be any one of continuous wave laser, argon-ion laser, and diode-pumped solid state laser (see column 9, lines 26-34, column 10, lines 44-56, and column 13, lines 43-53). Rodriguez et al. teach using different light detectors (photodetectors) that correspond to different fluorescence spectra by different dyes and fluorochromes (see column 8, lines 21-65 and column 10, line 57 to column 11, line 28). The analyzing portion counts and differentiates between erythrocytes (red cells), leucocytes (fluorescent material labeled subsets of white cells), and platelets (see column 5, lines 18-28 and column 7, line 58 to column 8, line 20). The analyzing portion provides a measure of hematocrit value based on size information of blood cells (MCV and RBC). According to Rodriguez et al., the analyzing portion corrects immunoassay result, such as for hemoglobin, based on blood cell counting results (MCH and RBC) (see column 8, lines 50-60 and column 14, lines 5-40). Optical information that is measured includes scattered light and fluorescence intensity from the analyte.

6. Claims 1-3, 5, 6, 8, 11, 14-16, 18, 19, 21, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Shingo (JP B 19349) (Abstract).

Shingo discloses an analyzer which comprises a sample preparing portion (reaction tank), a light source (semiconductor laser), a light detector (photodiode), and an analyzing portion (microcomputer). The sample preparing portion is configured to prepare a sample mixture by adding reagent to the sample. The reagent comprises carrier particles (polystyrene latex) having antibody or antigen immobilized thereto. Non-agglutinated single particles, i.e. blood cells, and agglutinated particles formed by the carrier particles in an immunoassay are differentiated by the analyzing portion according to their different optical information such as scattered light intensities.

7. Claims 1-3, 5-11, 14-16, and 18-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Oku et al. (US Patent 6,106,778).

Oku et al. disclose a compact combination blood cell count and immunoassay analyzer wherein the sample preparing portion is configured for preparation of split blood specimens, one for immunoassay section and the other for blood cell measuring section (see Abstract). The results of immunoassay, i.e. C-reactive protein (CRP), are corrected using a hematocrit value obtained by measurement of the number of blood cells (see column 1, line 62 to column 2, line 3 and 29-36; and column 7, lines 12-25). The analyzer in the immunoassay section also comprises a light source (light irradiating section), a light detector (light detection section) for detecting optical information from the immunoassay, and an analyzing portion (microcomputer with processor) for performing arithmetic computation from the measured optical information. Reagent

used in the immunoassay section comprises carrier particles having anti-CRP antibody immobilized thereto (latex immunoreagent). The analyzer in the blood cell count section is configured to count and differentiate between leucocytes (WBC), erythrocytes (RBC), platelets, and also configured to measure mean corpuscular volume (MCV), hematocrit (Hct), and hemoglobin (Hgb). The analyzer in the blood cell count section also comprises a light source, a light detector for detecting optical information (light scatter measurement) from the different cell populations, and an analyzing portion (microcomputer with processor) for performing arithmetic computation from the measured optical information (see column 4, lines 18-37 and column 5, lines 6-11).

8. For reasons aforementioned, no claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gailene R. Gabel
Patent Examiner
Art Unit 1641
August 4, 2006